

REMARKS

The pending Office Action addresses claims 61-65, 67-69, 71-89, and 95. Applicant appreciates the Examiner's allowance of claims 84-89 and 95, and the Examiner's indication that claims 66 and 72-74 represent allowable subject matter. Claims 61-65, 67-69, 71, and 75-83 stand rejected.

Amendments to the Claims

Applicants amend claim 72 to move the word "a" to the proper location. No new matter is added.

Rejection Pursuant to 35 U.S.C. §103

Claims 61, 62, and 67

The Examiner rejects claims 61, 62, and 67 pursuant to 35 U.S.C. §103(a) as being obvious over Kenna in view of U.S. Patent 5,084,050 of Draenert or U.S. Patent No. 5,725,529 of Nicholson et al. ("Nicholson").

Independent claim 61 recites a method for anchoring soft tissue within bone including drilling an opening into bone, inserting a stabilizing element into the bone opening, threading soft tissue through an aperture in an insertion element, and inserting the insertion element into the stabilizing element. A stem on the insertion element has a diameter greater than a diameter of an axial channel in the elongate sleeve of the stabilizing element such that the insertion element causes the stabilizing element to deformably expand and obtain a pressure fit within the bone opening.

The Examiner argues that Kenna discloses the claimed method, except for obtaining a pressure fit or compression fit within the bone opening. The Examiner relies on Draenert or Nicholson to teach devices that obtain a pressure or compression fit within a bone opening, arguing that it would have been obvious to modify the device of Kenna in view of Draenert or Nicholson to arrive at the claimed invention "in order to provide a more secure attachment to the same." Applicant respectfully disagrees.

Kenna is deficient in several aspects. Not only does Kenna fail to teach a method in which a pressure fit is obtained in bone, as admitted by the Examiner, Kenna also fails to teach a sleeve that *deformably expands*, and a stem having a diameter *greater* than a diameter of an axial channel of the sleeve. Kenna teaches a method of connecting two parts of a joint using a threaded first portion (30) and a second portion (32) having a nose (34). The second portion is secured in the first portion by locking

pins that are adapted to snap into and remain self-locked within a groove (33) formed in the first portion. No person having ordinary skill in the art would modify Kenna to increase the diameter of the second portion (32) of the device, to make the first portion (30) of the device deformably expandable, and to cause the two portions (30, 32) to obtain a pressure fit within bone when the portions are mated. These modifications would require almost all of the teachings of Kenna to be ignored and the device to be substantially reconstructed and redesigned. In particular, to modify Kenna as suggested by the Examiner, the nose of the second portion would need to be increased in diameter. This modification, however, would prevent the nose from being inserted into the first portion due to the pins on the nose. The pins would thus need to be removed. The first portion would also need to be made deformably expandable, to allow the first portion to expand when the second portion is inserted therein. There is nothing in Kenna that teaches or even suggests making the first portion deformably expandable. In fact, such a modification would interfere with the threads on the first portion, as the threads must be sufficient to engage bone. If the first portion were deformably expandable, the threads would deform upon insertion into bone. All of these proposed modifications would clearly require the device of Kenna to be entirely reconstructed and redesigned, thereby changing the principle of operation of Kenna. As set forth in the Manual of Patent Examining Procedure (MPEP), a proposed modification cannot change the principle operation of a reference. MPEP 2143.01(VI); see also *In re Ratti*, 270 F.2d 810 (CCPA 1959).

The Examiner's argument that one would be motivated to modify Kenna in view of Nicholson or Draenert "in order to provide a more secure attachment" between the first and second portions of Kenna is also misplaced. Kenna already provides a secure attachment between the first and second portions. As discussed above, the pins on the second portion extend into a groove on the first portion to securely lock the first and second portions together. The locking connection can only be unlocked by drilling into the device. See Col. 5, lines 20-23. Such an irreversible mechanical connection is likely more secure than a compression fit, which allows the components to be separated. Thus, there is likely no advantage to making the suggested modification. The use of a compression fit, as recited in claim 61, provides the advantage of fixing the stabilizing element within the bone hole by deformably expanding the stabilizing element into the bone. The first portion of Kenna has threads for mating to the bone, thus there is no need to deform the first portion into the bone to lock the device therein. Accordingly, a person having ordinary skill in the art would have no motivation to modify Kenna in view of Nicholson or Draenert.

Claim 61 therefore distinguishes over Kenna, Nicholson, and Draenert, taken alone or combined. Claims 62 and 67 are allowable at least because they depend from claim 61.

Claims 69, 75-80, and 82

Claims 69, 75-80, and 82 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over Kenna in view of Draenert or Nicholson, as applied to claims 61, 62, and 67, and further in view of U.S. Patent No. 5,725,529 of Li.

Claim 69 depends from claim 61, and therefore distinguishes over Kenna, Draenert, and Nicholson for the same reasons discussed above with respect to claim 61. Li is merely relied on by the Examiner to teach looping grafts through apertures, as claimed, thus Li does not remedy the deficiencies of these references. Claim 69 therefore represents allowable subject matter.

Independent claim 75 recites a method for replacing a torn ligament including the steps of obtaining a tendon graft, drilling a hole into bone, looping the tendon graft through an aperture in an insertion element, inserting a stabilizing element into the bone hole, and inserting the insertion element into the stabilizing element. Claim 75 further requires that the insertion element be held in the stabilizing element by compression fit. For the same reasons previously discussed with respect to claim 61, it would not have been obvious to a person having ordinary skill in the art to modify Kenna to use a compression fit, as taught by Nicholson and Draenert. As noted above, Li is merely relied on by the Examiner to teach looping grafts through apertures, as claimed, thus Li does not remedy the deficiencies of these references. Claim 75 therefore distinguishes over Kenna, Nicholson, Draenert, and Li, taken alone or combined, and represents allowable subject matter. Claims 76-80 and 82 are allowable at least because they depend from claim 75.

Claim 81

Claim 81 is rejected pursuant to 35 U.S.C. §103(a) as being obvious over Kenna, Draenert, Nicholson, and Li as applied to claims 69, 75-80, and 82, and further in view of Kenna or U.S. Patent No. 3,953,896 of Treace. Claim 81 depends from claim 75, and therefore distinguishes over Kenna, Draenert, and Nicholson for the same reasons discussed above with respect to claim 75. Kenna and Treace are merely relied on by the Examiner to teach the use of flanges, as claimed, thus Kenna and Treace do not remedy the deficiencies of these references. Claim 81 therefore represents allowable subject matter.

Conclusion

In view of the above amendments and remarks, Applicant submits that all claims are in

Serial No.: 10/623,212
Filing Date: July 18, 2003
Group Art Unit: 3738
Examiner: Paul B. Prebilic
Atty. Docket No.: 22956-233 (MIT-230DIV)

condition for allowance, and allowance thereof is respectfully requested. Applicant encourages the Examiner to telephone the undersigned in the event that such communication might expedite prosecution of this matter.

Respectfully submitted,

Date: June 19, 2003


Lisa Adams, Reg. No. 44,238
Attorney for Applicant

NUTTER, McCLENNEN & FISH, LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA 02110
Tel: (617) 439-2550
Fax: (617) 310-9550

1534964.1